

REMARKS

Applicants respectfully request reconsideration of the present application. No new matter has been added to the present application. Claims 1-51 have been rejected in the Office Action. Claims 1, 18, and 35 have been amended, no new claims have been added, and no claims have been canceled in this Amendment. Accordingly, claims 1-51 are pending herein. Claims 1-51 are believed to be in condition for allowance and such favorable action is respectfully requested.

Applicants' representative thanks the Examiner for granting a telephonic interview on February 27, 2007. During the interview, proposed amendments to the independent claims were discussed to clarify differences between the claimed invention and the cited references, namely U.S. Patent No. 6,671,563 to Engelson et al. (the "Engelson reference") and U.S. Patent No. 4,839,806 to Goldfischer et al. (the "Goldfischer reference"). In particular, it was noted that embodiments of the present invention provide medication administration comments at the place of administration of a medication to prevent medication administration errors and provide "five rights" compliance (e.g., ensuring the right medication is administered to the right patient). In embodiments, a medication administrator manually selects a medication intended to be administered to a patient from a list of displayed medications scheduled to be administered to the patient. Medication administration comments are provided to prevent medication administration errors, for instance, by allowing the medication administrator ensure that the actual medication to be administered to the patient matches the medication selected to be administered. In contrast, the Engelson reference discusses a system with a completely different mode of operation, in which a patient and a medication to be administered to the patient are specifically identified by the system by scanning bar codes associated with each. The system then checks the scanned patient and scanned medication against stored patient information to

automatically determine whether a discrepancy exists (e.g., whether the scanned medication is one scheduled to be administered to the scanned patient) and provides a generic alert if there is a discrepancy. Applicants noted these difference and that attempting to modify the Engelson reference (e.g., using the Goldfischer reference) in an attempt to achieve the claimed invention would improperly change the principle of operation in Engelson, as well as render the system in the Engelson reference unsatisfactory for its intended purpose. Applicants have amended the claims based on the discussion with the Examiner to clarify differences between the claimed invention and the Engelson and Goldfischer references. As such, Applicants respectfully submit that the pending claims are now in condition for allowance.

Amendments to the Claims

Claims 1, 18, and 35 have been amended in this Amendment. Care has been exercised to avoid the introduction of new matter. Support for the amendments to claims 1, 18, and 35 may be found in the Specification, for example, at col. 6, line 1-19; p. 11, lines 9-13.

Rejections based on 35 U.S.C. § 103

A. Applicable Authority

The basic requirements of a *prima facie* case of obviousness are summarized in MPEP § 2143 through § 2143.03. In order “[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success [in combining the references]. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both

be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).” See MPEP § 2143. Further, in establishing a *prima facie* case of obviousness, the initial burden is placed on the Examiner. “To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 USPQ 972, 972, (Bd. Pat App. & Inter. 1985).” *Id.* See also MPEP § 706.02(j) and § 2142.

B. Rejections based on Engelson and Goldfischer

Claims 1-51 have been rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over the Engelson and Goldfischer references. As the Engelson and Goldfischer references, alone or in combination, fail to teach or suggest all claim limitations of claims 1-51 and there is no suggestion or motivation to combine or otherwise modify the references to achieve the claimed invention, Applicants respectfully traverse this rejection, as hereinafter set forth.

Independent claim 1, as amended herein, recites a computer programmed method for providing one or more medication administration comments for preventing medication administration errors, wherein the one or more medication administration comments are provided at a place of administration of a medication in a hospital setting. The method comprises accepting a medication administrator identification for a medication administrator and accepting a patient identification for a patient. The method further comprises displaying a graphical user interface listing one or more medications scheduled for administration to the patient and accepting a user selection of one of the listed medications from the medication administrator, the selected medication corresponding with a medication to be administered to the patient by the

medication administrator. A data store is provided having a plurality of compliance rules, each of the compliance rules comprising a respective medication, a respective condition for the compliance rule, and one or more respective medication administration comments specific to the respective medication. It is determined whether a condition for at least of the compliance rules has been satisfied, where the compliance rule relates to the selected medication and has one or more associated medication administration comments for preventing medication administration errors. At the place of administration of the medication in a hospital setting, the one or more medication administration comments associated with the compliance rule are displayed on a display device when the condition has been satisfied. Displaying the one or more medication administration comments associated with the compliance rule at the place of administration of the medication in a hospital setting enables hospitals to reduce medication errors by electronically providing valuable and comprehensive medication information needed to improve the safety and quality of the care of the patient at the time and place the medication is to be actually administered to the patient.

By way of contrast, the Engelson reference discusses a care management system for managing the administration of care to patients. *See Engelson*, col. 2, lines 31-34. The system provides for automatically verifying that the right medication is being dispensed to the right patient in the right dosage via the right delivery route at the right time by maintaining a database of information regarding the patient. *See id.*, col. 2, lines 54-59. In operation, a patient and medication to be administered to the patient are specifically identified by the system by scanning a barcode associated with the patient and a barcode associated with the medication. *See id.*, col. 13, lines 22-32. The system analyzes the data to verify that the right medication is being given to the right patient in the right dose by the right route and at the right time. *See id.*, col. 13,

lines 49-54. If a discrepancy is determined, the system provides an alert. *See id.*, col. 13, lines 54-60.

Applicants respectfully submit that the Engelson reference fails to teach or suggest all limitations recited in independent claim 1. For example, the Engelson reference fails to teach or suggest “accepting a user selection of one of the listed medications from the medication administrator.” In particular, the specification of the present application indicates that a medication administrator selects a specific medication displayed in a list of medications to be administered to the patient (e.g., using a keyboard or mouse as is known in the art). *See, e.g.*, p. 11, lines 9-13. In contrast, the system in the Engelson reference is directed to the system determining the medication to be administered based on the scanning of a bar code on a medication. As such, the approach in the Engelson is different from a user selecting a medication from a list of medications as recited by independent claim 1.

Additionally, the Engelson reference fails to teach or suggest “providing a data store having a plurality of compliance rules, each of the compliance rules comprising a respective medication, a respective condition for the compliance rule, and one or more respective medication administration comments specific to the respective medication.” The system in the Engelson reference simply fails to include such compliance rules. Instead, the Engelson reference merely discusses discrepancy checking wherein a medication to be administered to a patient is checked against stored information for the patient to determine whether a discrepancy exists (e.g., whether the medication is one scheduled to be administered to the patient). This is significantly different from the invention of claim 1 in which a plurality of compliance rules are provided that each include a medication, a condition for the compliance rule, and a comment specific to the medication for the compliance rule. This difference is significant as the invention

of claim 1 provides substantial advantages over the system of the Engelson reference by being able to provide medication administration comments that go beyond just a discrepancy warning. As such, the invention of claim 1 advances the state of the art beyond what is described in the Engelson reference.

Because the Engelson reference fails to describe providing compliance rules as described above, the Engelson reference necessarily also fails to describe “determining if a condition for a compliance rule has been satisfied, wherein the compliance rule relates to the selected medication and has one or more associated medication administration comments for preventing medication administration errors” and “displaying at the place of administration of the medication in a hospital setting, on a display device, the one or more medication administration comments associated with the compliance rule when the condition has been satisfied.”

The Office Action admits that the Engelson reference fails to teach or suggest multiple limitations of independent claim 1 and cites the Goldfischer reference. However, the Goldfischer reference fails to cure the deficiencies of the Engelson reference. For example, the Goldfischer reference fails to teach or suggest, “providing a data store having a plurality of compliance rules, each of the compliance rules comprising a respective medication, a respective condition for the compliance rule, and one or more respective medication administration comments specific to the respective medication.” Instead, in the Goldfischer reference discusses a portable, hand-held computer carried by a nurse during rounds. The hand-held computer is a stand-alone device, to which medication information for patients is transferred and stored before the nurse begins rounds. The medication information does not comprise a plurality of

compliance rules, each compliance rule including a respective medication, condition, and medication administration comments.

Because the Goldfischer reference fails to describe providing compliance rules as described above, the Goldfischer reference necessarily also fails to describe “determining if a condition for a compliance rule has been satisfied, wherein the compliance rule relates to the selected medication and has one or more associated medication administration comments for preventing medication administration errors” and “displaying at the place of administration of the medication in a hospital setting, on a display device, the one or more medication administration comments associated with the compliance rule when the condition has been satisfied.”

Further, Applicants respectfully submit that there is no suggestion or motivation to modify the Engelson reference with the Goldfischer reference because the modification would render the invention in the Engelson reference unsatisfactory for its intended purpose. “If [a] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).” MPEP § 2143.01. The intended purpose of the system in the Engelson reference is to automate the process of administering a medication to a patient to ensure the right medication is administered to the right patient. In particular, the system in the Engelson reference removes human error by the system identifying the actual medication to be administered via a bar code. As such, the system can check if the scanned medication is one that is scheduled to be administered to the patient. *See, e.g.*, Engelson, Abstract; col. 2, line 54 – col. 3, line 6; col. 13, 28-32. The Office Action attempts to modify the Engelson reference with the Goldfischer reference in an attempt to achieve the

invention of claim 1. However, such a modification would require the system in the Engelson reference to receive a user selection of a listed medication (which may not correspond with the actual medication). However, the system in the Engelson reference intentionally automates the administration process and uses a bar code to identify the particular medication and remove potential human error of a user identifying an incorrect medication to the system. Accordingly, Applicants respectfully submit that the modification would render the system in the Engelson reference unsatisfactory for its intended purpose, and thus there is no suggestion or motivation to modify the Engelson reference with the Goldfischer reference.

Similarly, Applicants respectfully submit that there is no suggestion or motivation to modify the Engelson reference with the Goldfischer reference because the modification would change the principle of operation of the system in the Engelson reference. "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)." MPEP § 2143.01. The principle of operation of the system in the Engelson reference is to allow the system to identify the actual medication to be administered through use of a bar code associated with that medication. To modify the Engelson reference with the Goldfischer reference in an attempt to find claim 1 would destroy the principle of operation of the Engelson system because the system would not be able to identify the actual medication. Instead, a user would identify the medication by selecting from a list of medications. Accordingly, Applicants respectfully submit that the modification would change the principle of operation of the system in the Engelson reference, and thus there is no suggestion or motivation to modify the Engelson reference with the Goldfischer reference.

Accordingly, Applicants respectfully submit that there is no suggestion or motivation to combine the Engelson reference with the Goldfischer reference and that the references, either alone or in combination, fail to teach or suggest all of the limitations of independent claim 1. For at least these reasons, independent claim 1 is patentable over the Engelson and Goldfischer references. Accordingly, withdrawal of the 35 U.S.C. § 103(a) rejection of independent claim 1 is respectfully requested.

Each of independent claims 18 and 35, as amended herein, include elements similar to those recited in independent claim 1. As such, it is respectfully submitted that the Engelson and Goldfischer references fail to teach or suggest all limitations of independent claims 18 and 35, as amended herein, and there is no suggestion or motivation to combine or otherwise modify the references for at least the same reasons as noted above for independent claim 1. Independent claims 18 and 35 are patentable over the Engelson and Goldfischer references, and Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of independent claims 18 and 35.

Claims 2-17, 19-34, and 36-51 depend from independent claims 1, 18, and 35. Accordingly, these claims are believed to be in condition for allowance for at least the above-cited reasons. As such, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(e) rejections of claims 2-17, 19-34, and 36-51 as well. Dependent claims 2-17, 19-34, and 36-51 are believed to be in condition for allowance and such favorable action is respectfully requested.

CONCLUSION

Each of claims 1-51 is believed to be in condition for allowance, and a timely notice of allowance is solicited. Should it be determined that additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact Applicants' undersigned attorney.

The required \$790 fee associated with filing of the Request for Continued Examination is submitted herewith. The Commissioner is hereby authorized to charge any additional fee which may be required, or credit any overpayment, to Deposit Account No. 19-2112.

Respectfully submitted,

/John S. Golian/

John S. Golian
Reg. No. 54,702

SHOOK, HARDY & BACON L.L.P.
2555 Grand Boulevard
Kansas City, MO 64108-2613
816-474-6550